

REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 18-26 have been amended. Claims 30-33 are withdrawn. New claim 48 is presented, which corresponds to claim 19 in independent form. The total number of claims has not been increased, no new issues are raised, and no new matter is entered. Entry and favorable consideration of the claims presented herewith are respectfully requested.

I. THE INTERVIEW

At the outset, the undersigned wishes to thank the Examiner (Marsha Tsay) and her supervisor (Dr. Karen Cochrane Carlson) for kindly agreeing to conducting an interview on this application. The interview was held on October 6, 2005, and the courtesies extended by the Examiner and her supervisor were most appreciated. Prior to the interview, a copy of a draft amended set of claims was forwarded to the Examiner and her supervisor for review. Based on the outcome of the interview, the claims discussed during that interview are presented herewith. For the reasons discussed during the interview, it is believed that the claims obviate the outstanding formal and prior art rejections. Entry and favorable consideration of the claims presented herewith are accordingly respectfully requested.

II. THE 35 U.S.C. §101 REJECTION

Claims 34-38 stand rejected under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter. In response, claims 34-38 now refer to an isolated peptide, as

suggested by the Examiner. In addition, the terminology "consisting essentially of" no longer appears in the claims presented herewith.

Withdrawal of the outstanding 35 U.S.C. §101 rejection is now believed to be in order. Such action is respectfully requested.

III. THE 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION

Claims 18-47 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for the reasons discussed on pages 4 and 5 of the Action. In response, the claims have been amended to delete the terminology "having" and "consisting essentially of".

Claims 24 to 25, 27, 28, 39 to 41 and 46 to 47 now refer to a selected peptide being administered together with one or more other specified peptides. Claims 28 or 28 now refer to 'the' or 'each' peptide. Claim 30 is withdrawn from consideration. Claims 39 to 41 refer to a composition comprising a plurality of specified peptides. Claims 46 to 47 refer to a kit comprising a peptide or composition as previously claimed.

Claim 26 now refers to the peptide or peptides being administered by specified routes. The term 'orally' has been deleted. In addition, the term 'combination' has been deleted. The Examiner has raised issue in connection with the use of the term 'combination' of peptides in the claims and has also suggested that the way in which the peptides are combined has not been taught in the claims. In the amended claims it has been found possible to avoid the term 'combination' and it is believed therefore that the objection no longer applies. Nevertheless, it is submitted that the following remarks

show that an adequate explanation for the original term can be found in the application as filed.

Combining peptides for administration is described in the present application in the section headed (1) Specific therapy for Type 1 diabetes: the inventive solution at page 20. The selected synthetic peptides are said to be used singly or pooled into cocktails (thereby combining efficacies of individual selected peptides) and routes of administration and dosages are given by way of example. Administration of a number of peptides can of course be achieved either by separate administration of each or by the use of compositions i.e. mixtures of peptides.

This procedure is of general application when more than one peptide is used for administration in order to achieve the best outcome. Therefore it applies, for example, to the use of combinations of the peptides referred to at page 10 line 11, and to one of more of these in combination with peptides from 1A-2 (page 10 lines 16 to 18).

In the light of the above, it is submitted that the meaning of peptide 'combinations' would be clear to the person skilled in the art of peptide therapy.

The term 'or more' has been deleted from claims 27, 28 and 40.

The term 'or more' has been retained in claim 39 however. Claim 39 now refers to a composition comprising a first specified peptide and one or peptides from a group of three specified peptides. It will be clear to the skilled person that the composition could comprise a first peptide and one, two or three additional peptides.

Withdrawal of the 35 U.S.C. 112, second paragraph, rejection is now believed to be in order. Such action is respectfully requested.

IV. THE ANTICIPATION REJECTIONS

Claims 18, 26 to 29 stand rejected under 35 USC 102(b) as allegedly anticipated by Chance et al. The Examiner has acknowledged the Applicant's arguments but believes use of claim terminology "having" means that the claims are anticipated by the sequence in des (31-53) hP1. The term 'having' has been deleted without prejudice from the claims. As noted during the interview, claim 18 (and dependent claims 26 to 29) now refer to the administration of a peptide selected from the group consisting of QPLALEG SLQK (SEQ ID NO:9) and peptides extended therefrom by one or more amino acids bordering SEQ ID NO: 9 in the peptide GGGPGAGSLQPLALEGSLQKRGIVEQ (SEQ ID NO: 10).

The bridging peptide (SEQ ID NO: 1, page 7) is not administered in Chance. The formula which is administered in Chance et al is a much longer sequence (SEQ ID NO: 3, page 11), which includes the bridging peptide. It is believed that the claims are novel in view of Chance et al (arguments for non-obviousness were provided in our response dated April 27 2005).

Withdrawal of the anticipation rejection based on Chance et al is believed to be in order. Such action is respectfully requested.

Claims 34 to 38 stand rejected as allegedly anticipated under 35 USC 102(b) by Filvaroff et al (US 20020058614A1). The Examiner has acknowledged the Applicant's arguments but believes the use of 'consisting essentially of' allows for anticipation by SEQ ID NO: 13.

The term 'consisting essentially of' has been deleted without prejudice from the claims. Claims 34 to 38 now refer to specific peptides: SEQ ID NOs: 4,5,6 and 10. These sequences are not disclosed in Filvaroff.

V. THE OBVIOUSNESS REJECTION

Claims 34 to 38, 42 and 46 under 35 USC 103(a) stand rejected as allegedly unpatentable over Filvaroff. This rejection is rendered moot by the amendments and arguments presented above. Withdrawal of this rejection is respectfully requested.

VI. THE ASTILL THESIS

As noted during the interview, applicants have drawn attention to the published thesis by Tom Astill, which refers to the peptides of the present invention. The thesis was included in the Information Disclosure Statement filed on November 8, 2004. The Examiner indicated during the interview that she would review that document upon reconsideration of the application following receipt of a written response, and advise if anything further is required in light of that document.

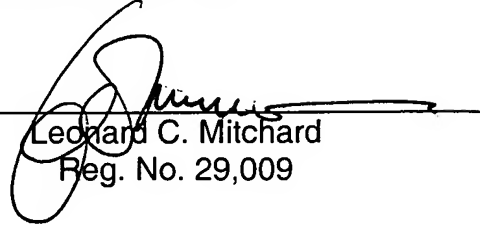
Favorable action on this application is awaited.

PEAKMAN, Mark
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Respectfully submitted,

NIXON & VANDERHYE P.C.

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